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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,262	03/25/2002	Alessandro Sencchi	TRUF101	2926

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EXAMINER

OH, SIMON J

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,262

Applicant(s)

SENECI ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 6 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Claims 9, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 17 both depend upon Claim 6, which in turn depends upon, in part, Claim 5. Claims 9 and 17 are defined to contain only active principles and hydrogenated fatty acids. However, this is not consistent with the scope of Claim 5, which requires the presence of excipients. This inconsistency of scope renders Claims 9 and 17 indefinite.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-13 under 35 U.S.C. 103(a) over Palepu *et al.* is hereby withdrawn.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada *et al.* (U.S. Patent No. 5,164,193)

The Okada *et al.* patent teaches sustained release tablet compositions and methods of making thereof. The disclosed compositions are primarily formulated from two main components: a first sustained release powder comprising an oil component and an active ingredient and a second sustained release powder comprising a water-soluble polymer and an active ingredient (See Abstract; and Column 1, Lines 49-60). Several types of oils may be used in the disclosed invention, including plant oils such as palm oil, as well as hydrogenated oils of

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plant origin. Although hydrogenated palm oil is not explicitly disclosed by name, it is the position of the examiner that the disclosure of the prior art makes this obvious (See Column 2, Lines 48-60). Various common tablet excipients may be included in the second powder, such as cellulosic polymers, gums, saccharides, and polyethylene glycol (See Column 4, Line 44 to Column 5, Line 4). A variety of active ingredients may also be used in the disclosed invention, such as anti-inflammatory drugs, skeletal muscle relaxants, plant preparations, and drugs for respiratory organs (See Column 3, Line 44 to Column 4, Line 6). The examples provided by Okada *et al.* clearly show that many different kinds of formulations with ingredients set in various proportions can be made from the disclosed invention (See Examples in Columns 6-12, particularly Example 4 and Table 6).

Regarding claim limitations drawn to granulator hole sizes and cooling temperatures, it is the position of the examiner that these limitations are not critical elements to the function of the instantly claimed invention. The examiner shifts the burden onto the applicant to provide a demonstration of criticality that such limitations bring unexpected results that would not be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made.

Response to Arguments

Applicant's arguments with respect to Claims 1-13 have been considered but are moot in view of the new grounds of rejection, presented above.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

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THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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